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10/585,120	05/29/2007	Lars Bo Poulsen	P71352US0	9910
136	7590	04/28/2009	EXAMINER	
JACOBSON HOLMAN PLLC			CHAPMAN, GINGER T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,120	Applicant(s) POULSEN ET AL.
	Examiner Ginger T. Chapman	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 January 2009 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/1450/B)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 13-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
2. This application contains claims directed to the following patentably distinct species:
3. Species 1: an appliance having a pre-filter comprising gas entrance and a gas exit, a gas channel and a number of constrictions comprising ribs and a gap at the constriction is smaller than the largest width of the constriction, as per claims 1-12 and 19-20.
4. Species 2: an appliance comprising pre-filters comprising a first, second and third surfaces with an inlet at the first surface and an outlet at the third, first and second distances, a gas path, and the second surface having at least one constrictive structure defining channels and the second surface and constrictive structure are positioned in the gas path a second distance from the first surface and the second distance is less than the first distance, as per claims 13-18
5. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Currently, these claims are generic to the named species.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another

species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the claims

6. Claims 12-20 are added, claim 1 is amended; claims 1-20 are pending in the application, claims 13-18 are withdrawn from consideration as being drawn to a nonelected species, claims 1-12 and 19-20.

Drawings

7. The drawings were received on January 23, 2009. These drawings are acceptable.

8. **Withdrawn objections:**

9. The objection to the drawings for not including reference numbers mentioned in the description and for different reference numbers for the same part, made of record in the previous Office action, is withdrawn in view of Applicants' amendment to the drawings.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1-12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (US 4,411,659) in view of Nystrup et al (WO 01/34072 A1).

13. With respect to claims 1 and 19, as best depicted in Figures 1 and 5-7, Jensen discloses an ostomy device comprising a collecting bag and a gas filtering assembly positioned in a gas path 17-23 from the an interior of the collecting bag to the surroundings (fig. 1), a pre-filter (fig. 6) and a gas filter 26 (figs 1 and 6), wherein the pre-filter (fig. 6) comprises a gas entrance 23 and a gas exit 42, and therebetween, a gas channel 25 (fig. 6) having two opposed, substantially liquid-impermeable surfaces 30, 35 defining there between a number of constrictions. 32, 33 each having a predetermined, largest width and a distance defining a gap between opposed surfaces permits gas flow more easily than non-gaseous flow (c. 4, ll. 25-45) (fig. 7).

14. Jensen discloses the claimed invention except for expressly disclosing the distance between the two opposed surfaces, at the constrictions, is significantly smaller than the largest width of the constriction. Because the drawings are not disclosed as to scale, the widths and distances cannot be determined from the drawings. Jensen teaches, at c. 5, ll. 4-8, that the constrictions, referred to as ribs in the cited passage, prevent obstruction of the gas pathway and filter. Jensen further teaches, at c. 5, ll. 15-18, that the constrictions / ribs prevent trap effluent, i.e. liquid and solid bodily waste in the spaces between the ribs before the effluent reaches and clogs the filter and directs the effluent to drain down into the collecting chamber of the ostomy bag. Jensen teaches that this allows gas to easily pass through an unclogged gas filter.

15. One of ordinary skill in the art at the time the invention was made would have recognized that if the distance between the constrictions /ribs is too wide, then solids would not be trapped within the ribs and would pass through the ribs to reach the filter and clog the filter. One of ordinary skill in the art at the time the invention was made would have also recognized that if the distance between the constrictions /ribs is too narrow, then solids would not be able to be trapped within the ribs to be directed to flow downward; instead the solids would build up against the surface of the pre-filter in the same manner that they would build up against the filter due to pressure of gas expanding within the bag. Thus the pre-filter would then be clogged by effluent thereby reducing the passage of gas through the pre-filter. Additionally, one of ordinary skill in the art would have recognized the benefit of optimizing the distance between the constrictions /ribs for their function as an effluent filter in the same manner that filters are known and designed in many sizes to separate a desired size of particulates from gas and fluid streams.

Thus, the parameter of filter “pore size” is a result-effective variable and as such, it would have been obvious to optimize. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Finally, the Federal Circuit has held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert denied*, 469 U.S. 830, 225 USPQ 232 (1984).

16. Jensen discloses the claimed invention except for expressly disclosing that gas flow through the gap is permitted more easily than non-gaseous material flow. The examiner notes the use of functional language and contends that the appliance of Jansen is fully capable of performing the recited function because Jensen, at c. 1, ll. 45-47, provides motivation to protect the filter against clogging, i.e. gas flow is permitted more easily than non-gaseous material flow. Jensen, at c. 4, ll. 25-35, teaches that gas flows through the gaps between the constrictions to be vented from the ostomy filter. Jensen teaches, at c. 4, ll. 35-45, that should non-gaseous material, i.e. liquid or semi-solid faecal matter the gaps / lateral spacing between the constrictions greatly reduce the possibility that the non-gaseous material will reach the filter. Therefore the examiner has a reasonable basis to contend that the appliance of Jensen is fully capable of performing the recited function.

17. In the alternative, Nystrup, at p. 11, l. 32 to p. 12, ll. 1-2, provides motivation to prevent clogging in an ostomy appliance such that non-gaseous material does not flow from the ostomy bag and clog the gas filter or gas valve. As best depicted in Figure 14, Nystrup teaches an

ostomy appliance having a gas entrance 8, 9 and a gas exit 10, gas channel (at arrows) defined by two surfaces 1, 3 defining therebetween a number of constrictions 26, 7 having width and distances defining gaps between the two opposed surfaces so that gas flow through the gap is permitted more easily than non-gaseous material flow (p. 12, ll. 1-2). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the pre-filter of Jansen as taught by Nystrup since Nystrup states, at p. 11, l. 32 to p. 12, ll. 1-2, that the benefit of forming the appliance with this design is that it prevents the gas filter and gas escape valve from being clogged.

18. With respect to claim 2, as best depicted in Figure 5, Jensen discloses the gas channel is oblong; see space between elements 33 and 32.

19. With respect to claim 3, as best depicted in Figure 5 and disclosed at c. 4, l.. 53-54, Jensen discloses at least one of the constrictions 32, 33 comprises a rib extending along one of the opposed surfaces.

20. With respect to claims 4 and 5, as best depicted in Figure 5, Jensen discloses the rib 32 extends along the direction of flow in the gas channel and wherein the rib 33 extends across the direction of flow in the gas channel.

21. With respect to claim 6, as best depicted in Figure 7 and disclosed at c. 4, ll. 60-67, Jensen discloses at least one constriction 33 has a cross section having, at one side thereof, a concave part 33a adapted to receive solid or liquid material.

22. With respect to claim 7, as best depicted in Figure 3 (16) and Figure 6 (30), Jensen discloses the constrictions are provided only at a predetermined area of the opposed surfaces.

23. With respect to claim 8, as best depicted in Figures 7 and 6, Jensen discloses the constrictions in the gas channel have different lengths, the longer constrictions being positioned closer to the entrance than the constrictions of shorter lengths.

24. With respect to claim 9, Jensen discloses at c. 4, ll. 53-54, the constrictions 32, 3 are provided as a monolithic element.

25. With respect to claim 10, as best depicted in Figures 6 and 7, Jensen discloses one of the opposed surfaces 33 is defined by part 23 of a wall 12 of the bag, and wherein the monolithic element 30 forms the other of the opposed surfaces 32 and further comprises means 43, 41, 42, 28 for engaging or attaching to the part 23 of the wall 12 so as to define the gas channel 25.

26. With respect to claim 11, Jensen teaches the monolithic element 30 is at least substantially flat having two main sides, teaching the element is a disc which is recognized to be substantially flat in the such manner that, by way of example, a coin is substantially flat and has two main sides, and having one or more constrictions 32, 33 on each of the two main sides (fig. 5 and at c. 4, ll. 56-59).

27. With respect to claim 12, Jensen discloses the claimed invention except for the distance of the gap is zero in a first state and greater than zero in a second state and the second state included a higher pressure within the gas channel. Nystrup, at p. 1, ll. 7-10, provides motivation for a gas entrance and gas exit permitting gas to exit the ostomy bag when gas pressure within the bag is high. As best depicted in Figure 14, Nystrup teaches a gas channel having two surfaces 1, 3 and constrictions 25, 26 therebetween and a distance defining a gap between the surfaces at the constrictions 25, 26 is zero in a first state and is greater than zero in a second state (p. 11, ll. 16-17). Therefore it would have been obvious to one having ordinary skill in the art at

the time the invention was made to form the distance of the gaps of Jensen as taught by Nystrup since Nystrup states, at p. 11, ll. 13-25, that the benefit of forming the pre-filter with this design is that when the gas pressure in the bag is low the canals are hardly visible but when the gas pressure in the bag is high, the constrictions grow by raising pressure and creates a gas channel which permits gas to flow out of the gas escape valve thereby relieving gas pressure within the bag.

28. With respect to claim 20, Jensen discloses the claimed invention except for a channel adjacent the constrictive structure. Jensen, at c. 1, ll. 15-16 and c. 2, ll. 25-28, provides motivation for a gas path for gas to flow through the filter without clogging. Nystrup, at p. 2, ll. 22-30, provides motivation for a gas path for gas to flow through a filter and exit the bag without clogging the filter in order to maintain gas flow. As best depicted in Figures 9, 10 and 14, Nystrup teaches channels (25 and arrows depicting gas flow). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide channels as taught by Nystrup in the appliance of Jensen since Nystrup states, at p. 3, ll. 24-26, that the benefit of such is that it allows gas flow out of the bag and the bag is easily emptied of gas.

Response to Arguments

29. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
04/16/09

/Tatyana Zalukaeva/
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